

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE: NATIONAL PRESCRIPTION</b>	)	<b>MDL NO. 2804</b>
<b>OPIATE LITIGATION</b>	)	
	)	<b>Case No. 1:17-md-2804</b>
<b>THIS DOCUMENT RELATES TO:</b>	)	
	)	<b>JUDGE DAN AARON POLSTER</b>
<i>City of Rochester v. Purdue Pharma L.P.,</i>	)	
No. 19-op-45853 (Track 12)	)	
	)	
<i>Lincoln County v. Richard S. Sackler, M.D.,</i>	)	
No. 20-op-45069 (Track 13)	)	
	)	
<i>City of Independence, Missouri v. Williams,</i>	)	
No. 19-op-45371 (Track 14)	)	
	)	
<i>County of Webb, Texas v. Purdue Pharma,</i>	)	
<i>L.P., No. 18-op-45175 (Track 15)</i>	)	
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**PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE TO  
AMEND AND SUPPLEMENT COMPLAINTS IN THE PBM BELLWETHER ACTIONS**

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## **INTRODUCTION**

Plaintiffs in these newly-designated bellwether cases seek leave to amend under Rule 15 to update their allegations and claims based on currently known information as to how the PBM Defendants helped fuel the opioid epidemic in Plaintiffs' communities. Leave to amend in this setting comports with Rules 15 and 16, as well as the Court's Orders and the Sixth Circuit's rulings on amendment, including specifically in bellwether cases, and should be granted.

Nothing in Defendants' Opposition supports their extraordinary position that no amendment should be allowed. They argue that the proposed amendments "come far too late," Opp. at 2, 7-8, which ignores or misconstrues the Court's Order (ECF 371) permitting amendment when a case is designated as a bellwether. Defendants also claim undue prejudice based on the complexity of the proposed amendments and the involvement of third parties, Opp. at 1-2, 10-11, even though this complexity is inherent in the structure and functions of PBMs themselves and is not grounds to deny leave to amend in any event. *See, e.g., Micron Techn., Inc. v. Rambus Inc.*, 409 F. Supp. 2d 552, 559 (D. Del. 2006) ("[I]t may be necessary to address case complexity in determining how to try the case, but that is not a basis for denying leave to amend in this matter.").

Defendants also challenge the proposed amendments pertaining to opioid dispensing as expanding these cases and going beyond the bellwether function. Opp. at 1, 8-9. This too is incorrect. Plaintiffs' claims against Defendants *as PBMs* have always involved their review of, and failure to restrain, in-network pharmacies' opioid dispensing. Motion at 7, 11. Dispensing thus is part of these cases with or without amendment. The inclusion, in the proposed amendments, of facts pertaining to Defendants' mail-order pharmacy dispensing simply provides a fuller picture of how these Defendants helped fuel the opioid epidemic in Plaintiffs' communities, without significantly expanding the substantive issues in the cases or the discovery they require. For all of

these reasons and as more fully set forth below, the motion for leave to amend should be granted in its entirety.

### **ARGUMENT**

#### **I. Plaintiffs Need Not Meet the “Good Cause” Standard of Rule 16, But that Standard Is Met in Any Event**

Under Rule 15, “the court should freely give leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). Here, justice plainly so requires. The four bellwether cases were stayed from May 2018 or when they were later transferred into the MDL until October 2023. ECF 371 (5/3/2018 Order) at 1 (staying non-bellwether cases); ECF 5231 (10/27/2023 Order) at 1-2 (designating these cases as bellwethers). Justice demands that Plaintiffs in these bellwethers be able to proceed based not just on information known four to five years ago, but on all currently known information about how the PBM Defendants contributed to the opioid epidemic.

Defendants try to avoid the foregoing by arguing that Rule 15 is inapposite and that “Rule 16’s ‘good cause’ requirement applies because Plaintiffs’ deadlines to amend the complaints passed years ago.” Opp. at 7. This is incorrect. Rule 16’s “good cause” standard applies where a scheduling order must be *modified*. Fed. R. Civ. P. 16(b)(4). Plaintiffs’ request to amend here does not seek to modify any of the Court’s Orders. The Court’s May 3, 2018 Order clarifying CMO-1 provides that “all cases not designated in paragraphs 2 or 3 of CMO-1 are stayed until further order of a Court” and that, “[i]f a case is later designated as a bellwether for motion practice or trial, a separate CMO will be entered that will provide for another opportunity to amend.” ECF 371 at 1. That is exactly what has happened here. In seeking to amend, Plaintiffs are effectuating, not modifying, the Court’s scheduling orders. The Rule 16 standard for modifying a scheduling order therefore does not apply.

Even if it did, leave should still be granted. These cases have been stayed for approximately five years, during which time this MDL focused on (and in almost every case resolved) claims against other categories of defendants. Even if it were true, as Defendants contend, that Plaintiffs had earlier opportunities to amend, it would have made no difference, as the cases would have remained stayed in any event. Orderly procedure to manage this MDL provides good cause for the Court to permit amendments of the PBM bellwether complaints at this time.

## **II. Plaintiffs' Proposed Amendments Are Not Unduly Prejudicial**

### **A. Defendants Are Not Prejudiced by the Timing of the Amended Complaints**

Defendants argue that, despite the clear statement in the Court's 2018 clarification of CMO 1 that amendments would be permitted at the time of bellwether selection, allowing amendment now would be unduly prejudicial. Opp. at 7. They are wrong. Their argument depends on the misapplication of authority about the potential prejudice of belated amendments. Where a party seeks to add new claims or new parties after a case has been actively litigated, a court may consider the extent to which such additions may be unduly prejudicial. *But that is not what happened here.* These cases have been stayed while the Court adjudicated other MDL cases. Prejudice arises not from the mere passage of time, but from how much a case has progressed. *See, e.g., In re Norplant Contraceptive Prods. Liab. Litig.*, 163 F.R.D. 255, 257 (E.D. Tex. 1995) ("Because this lawsuit is still in a relatively early stage of the proceedings, and because merits discovery in this case has been stayed pursuant to the Practice and Procedure Orders issued by this Court on December 14, 1994 and February 2, 1995, the addition of this misrepresentation claim will neither unduly delay the case nor unduly prejudice the Defendants."). Here, the cases have not progressed at all. Moreover, Defendants have always known that, when the Court chose MDL bellwethers for the claims against them, the plaintiffs selected would be given an opportunity to amend. In the meantime, the Defendants were not called upon to do anything to defend the earlier versions of

the claims asserted in the stayed complaints against them. They do not – and cannot -- explain what would have been different had the allegations in the amended complaints been added earlier. But if nothing has changed – they have expended neither time nor money defending the original claims, nor otherwise relied on the contents of the earlier pleadings -- there can be no prejudice. Because these cases are at the outset of active litigation, Defendants are not prejudiced by the addition of new parties or new claims.

Indeed, in *In re Nat'l Prescription Opiate Litig. (In re Meijer)*, 2022 WL 20701236 (6th Cir. Nov. 10, 2022), the Sixth Circuit expressly rejected the argument that the addition of new parties at the time of bellwether selection was unduly prejudicial where, as here, the addition was made before discovery commenced. *See id.* at \*1. Defendants try to distinguish *Meijer* with respect to the addition of new parties on the basis that *Meijer*, although a new defendant in the bellwether case, had previously been named in other cases in the MDL. This distinction might be relevant if the new defendants named in Plaintiffs' proposed pleadings in these cases were unrelated to the existing defendants, although even then, the addition of new parties before the commencement of discovery or motion practice would not be prejudicial. But here, all of the proposed new defendants are affiliated with the existing Defendants; they are part of the same corporate family. Plaintiffs have simply ensured that all relevant entities of these corporate families are now before the Court. This is not a cause of undue prejudice.

**B. The Scope of the Proposed Amendments Is Not Prejudicial and Is Commensurate with the Multi-Faceted Roles of the PBM Defendants**

Defendants claim that they will be prejudiced by the addition of both mail-order pharmacy dispenser claims and RICO claims, but they do not explain why these additions are unduly prejudicial *now*; their arguments, such as they are, would apply with equal force if Plaintiffs had originally pleaded these claims, and so are not a basis to deny amendment.



Moreover, Plaintiffs' amendments are commensurate in scope with the multi-faceted and far-reaching roles the PBM Defendants played in expanding the opioid supply. As Plaintiffs have explained, the complexities raised by the proposed amendments are "already inherent in these cases because of the complex and multi-faceted role played by the PBMs in the prescription drug market." Motion at 3. The PBM Defendants "contract with the manufacturers who make the drugs, the pharmacies who dispense them, and the third-party payors who pay for them." *Id.* at 6. These different capacities make the PBMs knowing participants in (a) spreading misinformation about the risks and benefits of opioids; (b) encouraging overuse of opioids through formulary placements that favor opioids and disfavor alternatives; (c) maintaining rather than restraining the free flow of opioids through misuse of concurrent Drug Utilization Review of in-network pharmacies' dispensing; and (d) failing to ensure that their own mail-order pharmacies maintain effective controls against diversion. *Id.* at 6-8.<sup>1</sup> The scope of Plaintiffs' amendments and their possible impact on third parties thus are appropriate in light of the facts these cases present.

Defendants try to use the complexity of their own business models and their relationships in the prescription drug distribution system as a shield against liability. *See Opp.* at 10. But complexity in this litigation is nothing new. The parties and the Court have managed procedural complexities throughout this unprecedented litigation. *See ECF 2676 (9/26/19 Order)* at 2

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<sup>1</sup> Plaintiffs are far from alone in observing that PBMs play expansive and complex roles in the prescription drug distribution system. *See, e.g., In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168, 179 (D. Mass. 2013) (recognizing the "complex and varied roles PBMs play in the billing, negotiating, and pricing of prescription drugs among pharmacies and manufacturers"); *Drug Mart Pharmacy Corp. v. Am. Home Prods. Corp.*, 472 F. Supp. 2d 385, 416 (E.D.N.Y. 2007) ("In the affiliated PBM context, the tripartite division of PBM organizational structures . . . conceals a complex web of corporate relationships . . . . It appears . . . that the affiliated PBM category is an amorphous one that serves as a catch-all for a variety of legal arrangements between PBMs that bargain for rebates and affiliated pharmacies that actually purchase [brand name prescription drugs].") (citations omitted).

(agreeing that “the combined Opioid Litigation [is] the most complex and important group of cases ever filed” and that the “magnitude and significance of the ‘opioid crisis’ and the Opioid Litigation cannot be overstated”). More fundamentally, the parties and the Court have managed this immense procedural complexity precisely because *this is not grounds for suppressing actionable claims*, by for example denying leave to amend.<sup>2</sup>

Defendants claim to see additional prejudice in Plaintiffs’ suggestion that their RICO claims need not necessarily be tried, but this is no more than a recognition that the addition of claims at the pleading stage is not dispositive of how a court may manage a case for trial. Moreover, discovery and motion practice on the RICO claims will provide both sides substantial guidance on the viability of these claims, regardless of whether or when they are tried. Because the complexity Defendants decry reflects their own business models, not any defect in Plaintiffs’ pleading, and since this is not grounds for denying amendment in any event, the motion for leave to amend should be granted.

Nor are Defendants correct that adding mail-order pharmacy claims is prejudicial because such claims “would swallow these PBM cases entirely.” Opp. at 8-9. This argument is wrong for two independent reasons. First, as Plaintiffs have already shown, Motion at 10, 11, , this Court has managed preparation for trial of bellwether cases involving Defendants that played multiple roles in the opioid distribution system. *See* ECF 2561 at 2-9 (addressing fraudulent marketing claims against Manufacturers and SOMS claims against Manufacturers and Distributors); ECF

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<sup>2</sup> *See, e.g., Micron Techn.*, 409 F. Supp. 2d at 559 (“Micron argues that allowing the amendments increases the complexity of the case. Perhaps that is so, and it may be necessary to address case complexity in determining how to try the case, but that is not a basis for denying leave to amend in this matter.”); *Studiengesellschaft Kohle mbH v. Novamont Corp.*, 485 F. Supp. 471, 477 (S.D.N.Y. 1980) (“The complexity of the issues and the desirability of resolving all disputes between the parties in a single action are also factors weighing in favor of granting leave to amend.”).

3261 at 2 (directing identification of bellwether cases for trial of claims against Pharmacy Defendants “in their roles as distributors and dispensers”).

Second, inclusion of the PBM Defendants’ role as mail-order dispensers will not significantly expand the issues or the scope of discovery. These cases already involve Defendants’ dispensing-related conduct as PBMs in performing utilization review of the opioid dispensing of the PBM Defendants’ tens of thousands of in-network pharmacies. *See* Motion at 7, 11. Indeed, Defendants’ argument, if accepted, would produce the peculiar result that their conduct with respect to prescriptions dispensed by *other* pharmacies would be fully at issue, while their conduct when they themselves were also the dispenser would be excluded. Moreover, Defendants fail to address how their role as mail-order pharmacies could ever be addressed if not in these cases. It would be unfair and unduly prejudicial *to Plaintiffs* to require them to split their opioid-related claims against these defendant families, even assuming they would be permitted to do so.

The same is true with respect to Defendants’ threat to implead multiple additional parties. Defendants do not and cannot explain why these additional parties would be relevant to mail-order dispensing claims, but not to the existing in-network pharmacy dispensing claims. As the Court is well aware, claims involving dispensing by other defendants were tried in this Court and in the CT4 bellwether case without the involvement of such parties.

Defendants’ argument that their mail-order pharmacies dispensed relatively small percentages of the opioids in Plaintiffs’ jurisdictions, *Opp.* at 9, similarly is not grounds to preclude claims by denying leave to amend. The Court has denied *summary judgment* on arguments based on purportedly small market share. *See, e.g.*, ECF 2559 (CT1 Order Denying Small Distributors’ Motion for Summary Judgment) at 3-5 (denying summary judgment for Distributor with 0.03% market share in bellwether county where “case law provides no hard and fast rule for assessing

whether a particular input is *de minimis*. In general, that is a determination for the trier of fact.”); *id.* at 5 (“[E]ven a very small proportional contribution by one of numerous defendants could equate with a rather large and substantial absolute quantity, both in monetary terms and in terms of the consequent harms.”). The Court’s analysis applies with even more force here, where mail-order pharmacy dispensing is one of multiple channels through which the PBM Defendants contributed to the oversupply of opioids in Plaintiffs’ communities.

### **III. The Proposed Amendments Do Not Violate the JPML’s Moratorium on New Transfers**

Separate and apart from their arguments about potential prejudice, none of which have merit, Defendants argue that Plaintiffs’ proposed addition of other affiliated entities as defendants circumvents the federal rules and/or the JPML’s orders. Opp. at 11. Again, Defendants are wrong. The federal rules treat naming additional parties identically to any other amendment. Fed. R. Civ. P. 16(b)(3)(A) (“The scheduling order must limit the time to join other parties, amend the pleadings, . . .”).<sup>3</sup> Because the CMO for these cases limits the time to amend, including by joining other parties, the federal rules’ requirements are satisfied.

Moreover, the JPML’s order on transfer of *future cases* is inapposite to amendment in these cases already before this Court. See *In re Nat’l Prescription Opiate Litig.*, 2022 U.S. Dist. LEXIS 65760, at \*2 (J.P.M.L. April 8, 2022) (“Based on our review of the progress of this litigation, we conclude that inclusion of these two actions *and any future actions* in MDL No. 2804 is no longer necessary to achieve the just and efficient conduct of the litigation.”). The JPML’s order says nothing about amendment in existing cases, which the federal rules and MDL statute make the

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<sup>3</sup> The decision in *Carrizo (Utica) LLC v. City of Girard, Ohio*, 661 Fed. Appx. 364 (6th Cir. Sept. 26, 2016), *see* Opp. at 11, is not to the contrary. There, the Court affirmed a district court’s denial of leave to amend sought after the scheduling order’s deadline, and indeed after the first phase of trial. 661 Fed. Appx. at 365. Here, by contrast, no deadline has passed; no trial proceeding has occurred; and the parties are in the earliest stages of discovery.

responsibility of this Court, not the Panel. 28 U.S.C. § 1407(b) (“Such coordinated or consolidated pretrial proceedings shall be conducted *by a judge or judges to whom such actions are assigned* by the [JPML].”) (emphasis added); *see also In re Asbestos Litig.*, 963 F. Supp. 247, 251 (S.D.N.Y. 1997) (“The court holding jurisdiction is empowered to conduct all pretrial proceedings by 28 U.S.C. § 1407(b). This power includes amendment of a complaint to add parties or claims.”).

#### **IV. Defendants’ Request to Sever Claims Relating to Their Mail-Order Dispensing Is Premature**

Seeming to recognize the infirmity of their arguments for prohibiting amendment, Defendants retreat to asking the Court to “sever and stay all mail-order pharmacy and other non-PBM claims.” Opp. at 13. This request, too, should be denied. As discussed, *supra*, the scope and complexity of issues Defendants rely upon in seeking to sever and stay claims is no greater than those the Court has managed throughout this litigation. *See* ECF 3261 (ordering bellwethers for trial of claims against Pharmacy Defendants “in their roles as distributors and dispensers”); ECF 2561 at 2-9 (ruling on summary judgment on causation as to fraudulent marketing and SOMS claims). Defendants do not show that severing and staying claims is warranted.

The request to sever and stay claims is also premature. These cases are still at the pleadings stage before discovery has even begun in earnest. Courts often hold that a request to sever claims or parties at this stage is inappropriate without the benefit of discovery to aid the required factual analysis.<sup>4</sup> That should be the case here, where severing and staying claims at this early stage would

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<sup>4</sup> *See, e.g., U.S. v. Private Sanitation Industry Ass’n*, 793 F. Supp. 1114, 1154 (E.D.N.Y. 1992) (civil RICO defendants’ motion to sever was premature where action had not proceeded beyond the pleading stage, and court was not yet able to sort out the intricacies of the relationships among the defendants); *see also Oram v. SoulCycle LLC*, 979 F. Supp. 2d 498, 505 (S.D.N.Y. 2013) (denying pre-discovery motion to sever claims as premature); *Montgomery v. STG Int’l, Inc.*, 532 F. Supp. 2d 29, 36 (D.D.C. 2008) (“[T]he record should be further developed through discovery. . . .”); *Martinez v. Robinson*, 2002 WL 424680, at \*2-3 (S.D.N.Y. March 19, 2002) (denying

provide no immediate streamlining or efficiency benefit.<sup>5</sup> The Court already has recognized, correctly, that discovery on Defendants’ mail order pharmacy opioid dispensing is likely necessary because it goes to the overarching question of knowledge relevant to all of Plaintiffs’ claims. *See* ECF 5265 (12/1/2023 Tr.) at 11:11-13 (“[T]here would be an ability to conduct discovery pertaining to dispensing practices – with respect to knowledge learned . . . .”); *id.* at 11:17-19 (“I understand that knowledge obtained through a portion . . . of their business . . . can go to other aspects of what they do.”). Since there will be discovery on mail-order pharmacy dispensing in any event, there is even less reason here than in the usual case to consider severing or staying claims in advance of discovery.

The same is true, as discussed above, with Defendants’ threat to implead additional parties if their conduct as mail-order dispensers is at issue. Such additional parties would be as relevant to Defendants’ review of in-network pharmacy dispensing, which is at issue with or without severing, as to their mail-order dispensing. If, during discovery, the mail-order dispenser claims somehow prove more complex, or to involve more parties, the Court can address severance at such time.

### **CONCLUSION**

For the reasons set forth herein and in Plaintiffs’ moving papers, the Motion for Leave to Amend and Supplement should be granted in its entirety.

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defendants’ motion to bifurcate claims and stay discovery where “[d]iscovery has barely begun, and, as a consequence, information necessary to evaluate the relevant factors is not yet available.”).

<sup>5</sup> The situation is different when the Court has severed unrelated *defendants*, rather than a portion of the claims against a defendant. With the former, there are likely efficiencies, for example in discovery, in which the severed defendant need not participate at all. By contrast, it is plainly more efficient for a defendant to participate in discovery involving all claims against it at one time, rather than artificially delineating which documents and witnesses pertain to which claims.

Dated: February 5, 2024

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 5, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

*s/Peter H. Weinberger*

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